4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Advisory Committee; Pharmaceutical Science and Clinical Pharmacology Advisory Committee (Formerly Known as the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology), Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee (formerly known as the Advisory Committee for Pharmaceutical Science and Clinical Pharmacology) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Pharmaceutical Science and Clinical Pharmacology Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the January 22, 2018.

DATES: Authority for the Pharmaceutical Science and Clinical Pharmacology Advisory Committee will expire on January 22, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, ACPS-CP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Pharmaceutical Science and Clinical Pharmacology Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Pharmaceutical Science and Clinical Pharmacology Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates scientific, clinical, and technical issues related to the safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases; the quality characteristics which such drugs purport or are represented to have, and as required, any other product for which the Food and Drug Administration has regulatory responsibility; and makes appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review Agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

The Committee shall consist of a core of 14 voting members including two Chairpersons. Members and Chairpersons are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical sciences (pharmaceutical manufacturing, bioequivalence research, laboratory analytical techniques, pharmaceutical chemistry, physiochemistry, biochemistry, molecular biology, immunology, microbiology);

clinical pharmacology (dose-response, pharmacokinetics-pharmacodynamics, modeling and simulation, pharmacogenomics, clinical trial design, pediatrics and special populations and innovative methods in drug development); biostatistics, related biomedical and pharmacological specialties, current good manufacturing practices, and quality systems implementation. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include up to three non-voting members who are identified with industry interests.

Further information regarding the most recent charter and other information can be found at:

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AdvisoryCommitteeforPharmaceuticalScienceandClinicalPharmacology/ucm107524.htm or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT).

Due to a change in the committee name, FDA will publish a final rule will in the Federal Register amending 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at http://www.fda.gov/AdvisoryCommittees/default.htm.

Dated: January 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Programs.

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